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No. 04-623

IN THE

Supreme Court of the United States

ALBERTO GONZALES, ATTORNEY GENERAL, *et al.*,

Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF OF *AMICI CURIAE* PRO-LIFE LEGAL DEFENSE FUND, LEGAL CENTER FOR DEFENSE OF LIFE, AND UNIVERSITY FACULTY FOR LIFE IN SUPPORT OF PETITIONERS

RICHARD F. COLLIER, JR.
Collier & Basil, P.C.
100 Thanet, P.O. Box 3720
Princeton, NJ 08543
(609) 924-2213

DWIGHT G. DUNCAN
Counsel of Record
333 Faunce Corner Road
North Dartmouth, MA 02747
(508) 998-9600

COLBE MAZZARELLA
265 Essex Street, Suite 202
Salem, MA 01970
(617) 569-5971

THOMAS M. HARVEY
One Constitution Center
Boston, MA 02129
(617) 886-0364

BATEMAN & SLADE, INC. BOSTON, MASSACHUSETTS

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INTEREST OF *AMICI CURIAE* [1]

The Pro-Life Legal Defense Fund, Inc. (PLLDF), a Massachusetts not-for-profit corporation, and the Legal Center for Defense of Life, Inc. (the "Legal Center"), a New Jersey not-for-profit corporation, both provide *pro bono* legal services for the protection of human life. University Faculty for Life (UFL) is a multidisciplinary association of scholars founded in 1989 to promote research, dialogue, and scholarship among faculty members on various topics in medical ethics including euthanasia. The PLLDF, Legal Center, and UFL strongly oppose the use of federally-regulated controlled substances to facilitate physician-assisted suicide, euthanasia, or eugenics. *Amici* respectfully submit this brief in support of the Petitioners and urge the Court to reverse the Ninth Circuit.

The PLLDF and Legal Center filed a joint brief, as friends of this Court, in *Washington v. Glucksberg*, 521 U.S. 702 (1997). *See* 1996 WL 656314. Here, as in *Glucksberg*, *amici*'s purpose in filing is to correct the historical errors of the Ninth Circuit's majority opinion. In *Glucksberg*, *amici* respectfully pointed out that the Ninth Circuit's "majority opinion distort[ed] the historical record in an apparent attempt to justify its creation of a new fundamental constitutional right." *Id.* at *5. Similarly, *amici* now respectfully point out that the Ninth Circuit's majority opinion has distorted the historical record of federal regulation of medicine and controlled substances in an apparent attempt to characterize this case as involving an exclusively "state issue." Because the Ninth Circuit based its holding on this erroneous premise, that court should once again be reversed.

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[1] Counsel for all four parties have consented to the filing of this *amicus* brief. Their consent letters are on file with the Clerk of the Court. No counsel for a party authored this brief in whole or in part.

SUMMARY OF ARGUMENT

The federal government has extensively regulated the practice of medicine and the distribution of controlled substances for over one hundred years. This longstanding and pervasive federal regulation belies any claim that this case involves an exclusively "state issue." As a result, the Ninth Circuit, which based its holding on the erroneous premise that controlled substances constitute "an area of law traditionally reserved for state authority," should be reversed.

An examination of the history of federal drug regulation demonstrates the Ninth Circuit's error. Interest in federal drug regulation arose contemporaneously with the interest in state regulation during the late nineteenth century. Congress provided the first comprehensive drug regulations in the *Pure Food and Drugs Act* of 1906 and delegated even greater authority to federal regulators under the *Federal Food, Drug, and Cosmetic Act* of 1938 (FFDCA). The FFDCA also established the precursor to the FDA, which now regulates one-quarter of the gross national product.

Moreover, Congress has regulated highly dangerous drugs extensively since the *Harrison Narcotics Act* of 1914. To provide even greater federal oversight, Congress passed the *Controlled Substances Act* of 1970 (CSA). The CSA is just one of over fifty pieces of legislation since 1914 pursuant to which federal agencies have enacted regulations governing controlled substances.

Federal regulations thus provide comprehensive and uniform standards for prescribing, dispensing, and using controlled substances and other dangerous drugs. Against this extensive regulatory background, a state cannot unilaterally decide to "opt out" of federal regulations. Allowing such an unprecedented circumvention of federal law for every state that disagrees with a federal policy would not only be antithetical to the Congressional objective of protecting public health and safety in this case, but also create an impracticable system of administrative law by establishing a precedent for future opt-outs.

ARGUMENT

I. THE NINTH CIRCUIT'S HOLDING RESTED ON THE ERRONEOUS PREMISE THAT DRUG REGULATIONS ARE A "STATE ISSUE."

The decision of the Ninth Circuit should be reversed because the majority's opinion failed to recognize that the federal government has regulated the practice of medicine and distribution of drugs extensively. The premise of the Ninth Circuit's opinion—that drug regulations involve "an area of law traditionally reserved for state authority"—is incorrect as a matter of both historical and current practice. For over one hundred years the federal government has regulated the prescription, distribution, and utilization of controlled substances and other dangerous drugs. The extensive federal regulation of this area of law thus belies any claim that this case involves an exclusively "state issue."

A. The Federal Government Has Extensively Regulated the Prescription, Distribution, and Utilization of Controlled Substances and Other Drugs For Over One Hundred Years.

Federal regulations have governed this area of medicine for over one hundred years and continue to do so today.[2] The *Import Drugs Act* (1848), *Pure Food and Drugs Act* (1906), *Harrison Narcotics Act* (1914), *Federal Food, Drug, and Cosmetic Act* (1938), and *Controlled Substances Act* (1970) are just a few of the many statutes under which

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[2] *See American Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y. 1987) ("Federal regulation of drug safety and efficacy is pervasive and complete."); *United States v. Gel Spice Co.*, 601 F. Supp. 1214, 1229 (E.D.N.Y. 1985) (noting the "pervasive nature of the federal regulation of the food and drug industry"); *United States v. New England Grocers Supply Co.*, 488 F. Supp. 230, 238 (D. Mass. 1980) (basing its holding on the "pervasive nature and long history of federal regulation of the food and drug industry").

executive agencies have established myriad regulations. The comprehensiveness of this federal regulatory system demonstrates the federal government's substantial and longstanding interest in protecting public health and maintaining public safety with regard to controlled substances and other dangerous drugs.

1. The *Import Drugs Act* (1848), *Pure Food and Drugs Act* (1906), and Early Federal Regulations

The "interest in federal regulation [of food and drugs] arose contemporaneously with interest in state regulation" during the late nineteenth century. Marc T. Law, *History of Food and Drug Regulation in the United States*, at 4 (2004). During the Reconstruction years, Congress established the U.S. Department of Agriculture Bureau of Chemistry, the predecessor to the Food and Drug Administration (FDA). Early federal regulations regarding the prescription, distribution, and utilization of drugs targeted specific issues of national importance such as importation and biologics. *See, e.g.*, *Import Drugs Act* of 1848, 30 Cong. Ch. 70, 9 Stat. 237 (1848) (curbing the import of adulterated medicines); *Biologics Control Act* of 1902, Pub. L. No. 57-244, 32 Stat. 328 (1902) (requiring the federal government to grant pre-market approval for every biological drug and for the process and facility producing such drugs).[3]

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[3] *See also* Wesley J. Heath, *America's First Drug Regulation Regime: The Rise and Fall of the Import Drug Act of 1848*, 59 Food & Drug L.J. 169, 199 (2004) ("Defeating critics who had argued that the federal government should not interfere with freedom of commerce, the [*Import Drugs Act* of 1848] had proven not only that regulation of some markets could be extremely beneficial but also that the federal government was a highly competent drug regulator. The 1848 law undoubtedly contributed greatly to Congress' confidence in the federal government's ability to regulate drugs.").

Before the emergence of a comprehensive federal regulatory system in 1906, most "[d]rugs could be bought and sold like any other consumer good." Mitchell S. Berger & Barry A. Berger, *FDA Overview, Introduction: History of Food and Drug Regulation*, at *1 (2003); *see also* Richard T. Hull, "Medical Ethics and Society," at *4 (1987) ("[T]here was virtually no regulation of medicines and remedies. Medicines containing narcotics, such as morphine and cocaine, were sold without restriction. Quack remedies—some claiming to cure cancer—and contaminated drugs were largely uncontrolled by the federal government.").

As a result, in the late nineteenth century, national interest grew in establishing a general and comprehensive system for regulating food and drugs. *See* Heath, *supra*, at 170 ("As continued industrialization and social change swept the nation throughout the later half of the nineteenth century, the federal government had no choice but to deconstruct its ad hoc governmental system and replace it with broad institutional structures."). By 1906, America was "ready for comprehensive drug regulation." *Id.* at 199.

Thus, following a long legislative battle,[4] Congress passed the *Pure Food and Drugs Act* of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906). The 1906 Act provided the statutory authorization necessary for a comprehensive system of food and drug regulation at the federal level. *See* Law, *supra*, at *1 ("Federal regulation of the industry began on a large scale in the early twentieth century when Congress enacted the Pure Food and Drugs Act of 1906.").

The 1906 Act "banned the manufacture and distribution of adulterated and misbranded food and drugs" and prohibited "false and misleading advertising of food and drugs." Charles J. Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices*, 48

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[4] *See* Law, *supra*, at *4 (noting that "conflict among competing interest groups regarding the provisions of a federal law made it difficult to build an effective political constituency").

Rutgers L. Rev. 883, 891 (1996). Violation of the Act could result in "seizure of non-conforming goods or criminal penalties against those responsible for the violation." *Id.* The Act also recognized both the *U.S. Pharmacopoeia*, (established in 1820) and *National Formulary* (originally published in 1888) as "official standards for the strength, quality, and purity of drugs and for the tests to make such determinations." Daniel B. Klein & Alexander Tabarrrok, *History of Federal Regulation: 1902-Present*, at *2 (2001). As a result, the 1906 Act established the first comprehensive system of drug regulations and set the stage for future federal regulations. *See United States v. Articles of Drug (Lannett)*, 585 F.2d 575, 577 (3d Cir. 1978) ("Federal regulation of the drug industry may be traced to the passage of the Pure Food and Drug Act of 1906.").[5]

At the same time, Congress also turned its attention to establishing federal regulations for biological drugs. Federal regulation of human biologics began in 1902 when Congress enacted the *Biologics Control Act*, Pub. L. No. 57-244, 32 Stat. 328 (1902). The Act required that the federal government grant premarket approval for every biological drug and for every process and facility producing such drugs. *See Grand Labs., Inc. v. Harris*, 644 F.2d 729, 732 (8th Cir. 1981) (stating that the Act "prohibit[ed] the importation or interstate shipment of any virus, serum, toxin, antitoxin, or analogous products unless licensed by the Treasury

[5] Responsibility for enforcing the *Pure Food and Drugs Act* of 1906 fell to the Bureau of Chemistry, a division of the United States Department of Agriculture (USDA), which conducted some of earliest studies regarding food and drugs in the United States. The USDA's Division of Chemistry was established by President Abraham Lincoln in 1862. In 1901 the Division became the Bureau of Chemistry, which in 1927 became the Food, Drug and Insecticide Administration, which subsequently became the FDA in 1931. *See* Law, *supra*, at *5. The FDA currently regulates products accounting for approximately twenty-five percent of the United States gross national product, has over nine thousand employees, and has a total budget of over $1.4 billion. *See* Berger & Berger, *supra*, at *1, 6.

Department and properly labeled."). In 1913, Congress amended the 1902 Act by passing the *Virus, Serum & Toxin Act* of 1913, Pub. L. No. 66-430, 31 Stat. 828 (1912). As a result, the federal regulation of biological drugs, like the regulation of other drugs under the *Pure Food and Drugs Act* of 1906, was well-established even prior to the First World War. *See* Edward L. Korwek, *Human Biological Drug Regulation*, 50 Food & Drug L.J. 123, 124 (1995) (pointing out the "long history of biologics regulation, beginning in 1902 with the Virus, Serum, and Antitoxin Act" and noting that "such a ninety-year history, even with an emphasis on the last fifty years, cannot be easily reduced to a few pages of text").

2. The *Federal Food, Drug, and Cosmetic Act* (1938) and New Deal Regulations

The federal regulation of food and drugs continued to increase significantly during the New Deal. *See generally* Charles O. Jackson, *Food and Drug Legislation in the New Deal* (1970). During the early 1930s, Congress "weighed and rejected several bills aimed at improving existing federal regulation of drugs." Walsh & Pyrich, *supra*, at 893. In 1937, however, over one hundred people (mostly children) died as the result of ingesting a drug known as Elixir Sulfanilamide. The public outcry over the incident "spurred Congress to undertake the necessary process of reforming federal drug law." *Id.*; *see also* Klein & Tabarrok, *supra*, at *3 (noting that the Elixir Sulfanilamide tragedy demonstrated to Congress that "unfettered markets cause reckless injury and that public safety called for additional laws").

As a result, in 1938 Congress strengthened the federal government's power to protect the public from dangerous drugs by enacting the *Federal Food, Drug, and Cosmetic Act* of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified

at 21 U.S.C. §§ 301-392 (2000)). This Court has described the 1938 Act's pervasive reach and severe penalties:

> The 1938 Act, which established a system of premarketing clearance of drugs, prohibited the introduction into commerce of any "new drug" unless a new drug application (NDA) filed with the Food and Drug Administration (FDA) was effective with respect to that drug. . . . The Government could sue to enjoin violations, prosecute criminally, and seize and condemn the articles.

Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 612-613 (1973); *see also F.D.A. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134 (2000) ("[T]he Act generally requires the FDA to prevent the marketing of any drug or device where the 'potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.'") (quoting *United States* v. *Rutherford*, 442 U.S. 544, 556 (1979)).[6]

Thus, under the *Federal Food, Drug, and Cosmetic Act* of 1938, the federal government was "given considerably greater authority over the food and drug industry." Law, *supra*, at *6; *see also* Klein & Tabarrok, *supra*, at *4 (pointing out that because of the broad construction the courts have given to the interstate commerce clause, "in practice the [Act] regulates every drug"). The

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[6] *See also* Berger & Berger, *supra*, at *2 ("Among other things, the 1938 Act did the following: compelled manufacturers to demonstrate to the FDA the safety of new drugs prior to marketing; allowed the FDA to inspect manufacturing facilities; set tolerances for certain substances such as pesticides; extended FDA regulation to color additives and cosmetics; allowed the FDA to seek injunctions from courts; and provided detailed legal definitions of drug, devices, cosmetics, and labeling.").

"developments of this early period set a precedent for federal government activism in medicine." *Id.* at 3.

3. The *Harrison Narcotics Act* (1914) and *Controlled Substances Act* (1970)

The comprehensive federal regulation of narcotics, controlled substances, and other highly dangerous drugs began (but certainly did not end) with the *Harrison Narcotics Act* of 1914, Pub. L. No. 63-223, 38 Stat. 785 (1914). Indeed, according to a 1970 Congressional report: "Since 1914 the Congress has enacted more than fifty pieces of legislation relating to control and diversion, from legitimate channels, of those drugs referred to as narcotic and dangerous drugs." H.R. Rep. No. 91-1444 (1970), *reprinted in* 1971 U.S.C.C.A.N. 4566, 4601. The provisions of the *Harrison Act* and subsequent legislation were consolidated in the *Controlled Substances Act* of 1970.

Congress enacted the *Harrison Narcotics Act* of 1914 to limit the distribution of cocaine and heroin to health care professionals and to regulate the free use that had been in effect prior to the statute. *See* Klein & Tabarrrok, *supra*, at *3 ("The *Harrison Narcotics Act* of 1914 placed a tax on the production, sale, and use of opium and required prescriptions for products exceeding the allowable limit of narcotics. This act also mandated increased record keeping for physicians and pharmacists who dispense narcotics."). In 1919, the Supreme Court expansively interpreted the *Harrison Act* to prohibit any distribution of these drugs and held that such distribution was criminal. *See Webb v. United States*, 249 U.S. 96, 99-100 (1919).

The *Harrison Narcotics Act* of 1914 became the foundation for the federal regulation of controlled substances and dangerous drugs. *See* Martin Alan Greenberg, *Prohibition Enforcement* 6 (1999) ("For more than 50 years, this federal statute was the main basis of narcotics regulation in the U.S. as interpreted by the Supreme Court.").

Congress, however, continued to enact legislation—over fifty statutes between 1914 and 1970—to provide even more federal oversight of narcotics and controlled substances. *See* H.R. Rep. No. 91-1444 (1970), *reprinted in* 1971 U.S.C.C.A.N. 4566, 4601.

The laws and various amendments related to the *Harrison Narcotics Act* were consolidated and reinforced in the *Comprehensive Drug Abuse Prevention and Control Act* of 1970, Pub. L. No. 9-513, 84 Stat. 236 (1970). As Title II of this Act, Congress enacted the *Controlled Substances Act* (CSA), 1970, Pub. L. No. 91-513, 84 Stat. 1242 (1970) (codified at 21 U.S.C. §§ 801-904 (2000), under which it is "unlawful to prescribe or dispense controlled substances without a federal registration." *Oregon v. Ashcroft*, 368 F.3d 1118, 1121 (9th Cir. 2004) (citing 21 U.S.C. § 841(a)(1)).

The CSA prohibits physicians from dispensing and prescribing controlled substances except for legitimate medical purposes. *See* 21 C.F.R. § 1306.04(a) ("A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose."); *United States v. Moore*, 423 U.S. 122, 124 (1975) (holding that physicians violate the CSA "when their activities fall outside the usual course of professional practice"); *United States v. Kaplan*, 895 F.2d 618, 619 (9th Cir. 1990) (stating that the CSA prohibits "prescribing controlled substances for reasons other than legitimate medical purposes").

Moreover, as the Ninth Circuit's majority admits, "[i]n 1984, Congress amended the CSA to give broader authority to the Attorney General" in a provision that "gives the Attorney General new discretion over the registration of health care practitioners." *Ashcroft*, 368 F.3d at 1122. "The Attorney General is now authorized to revoke a physician's prescription privileges upon his determination that the physician has 'committed such acts as would render his registration . . . inconsistent with the public interest[.]'" *Id.* (citing 21 U.S.C. § 824(a)(4)). Overall, the *Controlled Substances Act* significantly enhanced federal regulatory

power because it reflected a "fundamental change in interpretation of the [C]ommerce [C]lause of the Constitution, thus eliminating the need to portray a police function as a revenue measure." Greenberg, *supra*, at 6.

4. *Durham-Humphrey Amendment* (1951), *Kefauver-Harris Amendments* (1962), and *Medical Device Amendments* (1976)

Meanwhile, federal regulation of those drugs regulated under the *Federal Food, Drugs, and Cosmetic Act* of 1938 continued during the post-World War II years.[7] Indeed, since its enactment, "the 1938 Act has been amended more than twenty times." Walsh & Pyrich, *supra*, at 896. The general trend in amendments to the Act has been to "increase the coverage of the Act or to increase the substantive authority granted to the FDA over products already within its jurisdiction." *Id.* at 896 n.35 (citing Richard A. Merrill & Peter Barton Hutt, *Food and Drug Law* 5 (1980)). Among the most significant reforms were the *Durham-Humphrey Amendment* of 1951, the *Kefauver-Harris Amendments* of 1962, and the *Medical Device Amendments* of 1976. *See id.* ("These revisions laid the final building blocks for the comprehensive system of drug and medical device regulation that exists today.").

Disagreements over whether certain drugs required a physician's prescription led to the *Durham-Humphrey Amendment* of 1951, 82 Cong. Ch. 578, 65 Stat. 648 (1951). The *Durham-Humphrey Amendment* permitted a drug to be sold directly to patients "unless, because of its toxicity or other potential for harmful effect or because the method of

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[7] *See* Klein & Tabarrok, *supra*, at *5 ("In the post-World War II era, the field of pharmacology entered a new age. People with bacterial illnesses could now be treated with a host of new antibiotics, and diabetics were likewise given the life-saving invention of insulin. In the 1950s in particular, many new drugs were called 'magic bullets' because of their potency and swift defeat of disease. The very success of the new drugs, however, spurred new regulations.").

collateral measures necessary to its use, it may be sold and used only under the supervision of a practitioner." Law, *supra*, at *6-7. The 1951 Act thus delineated a clearer distinction between prescription and over-the-counter drugs, and, under federal law, "[m]any important drugs could be sold only by prescription from a licensed practitioner." Klein & Tabarrok, *supra*, at *5.

The "most significant expansion" in FDA authority over drugs in this period, however, occurred when Congress enacted the *Kefauver-Harris Amendments* of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962). Law, *supra*, at *7. In response to the thalidomide birth-defect tragedy,[8] Congress passed the *Kefauver-Harris Amendments*, which "require[d] drug companies to conduct and submit tests determining safety and efficacy." Klein & Tabarrok, *supra*, at *6. In addition, federal regulators now had to "preclear all human trials, drug advertising, and labeling." *Id.*[9]

In the post-World War II era, the federal regulation of medical devices also became a prominent issue. *See* Klein & Tabarrok, *supra*, at *7 ("As with drugs, the field of medical devices entered a new era after World War II."). As medical devices became "more common and more complex," it

[8] *See* Klein & Tabarrok, *supra*, at *6 (describing how the West German pharmaceutical thalidomide, which by 1962 had been sold in forty-six countries (although not the United States), caused severe birth defects, including truncated limbs, in thousands of newborn babies).

[9] *See also* Berger & Berger, *supra*, at *3 ("Among other things, the amendment requires drug manufacturers to show the effectiveness of their products as well as their safety, to report adverse events to the FDA, and to ensure that their advertisements to physicians disclose the risks as well as the benefits of their products. Informed consent was required from participants in clinical studies. The FDA also was given jurisdiction over prescription drug advertising. In addition, the agency was required to approve a regulatory submission known as a new drug application before a company could market a new drug and be allowed to issue good manufacturing practice guidelines governing how drugs were to be manufactured. Inspection of drug manufacturers was mandated every 2 years.").

became apparent "that some sort of federal safety regulation was necessary." Walsh & Pyrich, *supra*, at 902. In response, Congress passed the *Medical Device Amendments* of 1976, Pub. L. No. 94-295, 90 Stat. 579 (1976) to provide a comprehensive and uniform system of federal regulation over medical devices. With the passage of the *Medical Device Amendments*, federal regulators "achieved jurisdiction over nearly every commercial implement or substance used in the treatment or diagnosis of disease." Walsh & Pyrich, *supra*, at 903. The federal government has continued to regulate medical devices extensively to ensure public health and safety. *See, e.g.*, *Safe Medical Devices Act* of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990) (substantially increasing reporting requirements for medical devices); *Mammography Quality Standards Act* of 1992, Pub. L. No. 102-539, 106 Stat. 3547 (1992) (ensuring that mammography facilities are certified and inspected).

5. Federal Regulations Under Ford, Carter, Reagan, Bush, Clinton, and Bush

Following the *Controlled Substances Act* of 1970, Congress continued to regulate controlled substances and other dangerous drugs under both the Ford and Carter administrations. *See, e.g.*, *Toxic Substances Control Act* of 1976, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (requiring premarket notification for chemical substances); *Psychotropic Substances Act* of 1978, Pub. L. No. 95-633, 92 Stat. 3768 (1978) (controlling illicit trafficking of psychotropic substances across national borders); *see also Medical Device Amendments* of 1976, Pub. L. No. 94-295, 90 Stat. 579 (1976). However, it was under the Reagan administration (despite its proclivity for deregulation) that Congress enacted a number of new statutes that further

extended the already pervasive federal oversight of controlled substances and other drugs.[10]

Likewise, under President Clinton, Congress attempted to modernize drug regulation through the *Food and Drug Modernization Act* of 1997, Pub. L. No. 105-115, 111 Stat. 2310, § 115(a) (1997). The *Food and Drug Modernization Act* established "fast-track approval for certain new drugs and accelerated approval for innovative devices by exempting certain devices from premarket notification requirements." Berger & Berger, *supra*, at 5. The Act also allowed federal regulators "to use expert panels in the drug approval process, regulated health claims in food, reauthorized [a previous prescription drug statute], and provided additional marketing exclusivity time to companies that conducted pediatric studies." *Id.* at 5-6.

As the United States entered the twenty-first century, the importance of federal regulation over controlled substances and other drugs was made frighteningly clear. In response to the attacks of September 11, 2001 and the subsequent anthrax scares, Congress enacted the *Public Health Security and Bioterrorism Preparedness Act* of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002). The *Bioterrorism Act* provides federal regulators with "significant new authority" for regulating the nation's food and drug supply. Berger & Berger, *supra*, at *61.

Overall, the comprehensive federal regulation of controlled substances and other drugs from the *Food and Drug Act* of 1906 to the *Public Health Security and*

[10] *See, e.g.*, *Federal Anti-Tampering Act* of 1983, Pub. L. No. 98-127, 97 Stat. 838 (1983); *Dangerous Drug Diversion Control Act* of 1984, Pub. L. No. 98-473, 98 Stat. 2070 (1984); *Narcotics Penalties and Enforcement Act* of 1986, Pub. L. No. 99-570, 100 Stat. 3207-2 (1986); *Controlled Substances Analogue Enforcement Act* of 1986, Pub. L. No. 99-570, 100 Stat. 3207-16 (1986); *Drug Export Amendments Act* of 1986, Pub. L. No. 99-660, 100 Stat. 3743, §351(h)(I)(B)(i) (1986); *Prescription Drug Marketing Act* of 1987, Pub. L. No. 100-293, 102 Stat. 95 (1987); *Chemical Diversion and Trafficking Act* of 1988, Pub. L. No. 100-690, 102 Stat. 4312 (1988).

Bioterrorism Preparedness Act of 2002 demonstrates not only the extent but also the importance of uniform federal regulations in protecting public health and safety. Indeed, the "pervasive nature and long history of federal regulation of the food and drug industry" are undeniable. *New England Grocers Supply Co.*, 488 F. Supp. at 238; *see also American Home Prods. Corp.*, 672 F. Supp. at 145 ("Federal regulation of drug safety and efficacy is pervasive and complete.").

B. The Pervasive Federal Regulation of Controlled Substances and Other Dangerous Drugs Belies Any Claim That This is a "State Issue."

The comprehensive federal regulations described above belie any claim that this case involves "an area of law traditionally reserved for state authority." *Ashcroft*, 368 F.3d at 1125. Indeed, federal drug regulations provide uniform standards for prescribing, dispensing, and using controlled substances. As a result, a State cannot "opt out" of federal drug regulations. Allowing such a circumvention of federal law would set a dangerous precedent for future opt-outs.

It is black-letter law that "[w]ith regard to federal regulation, Congress undoubtedly possesses the authority to proscribe drugs it considers dangerous to the public welfare." 25 Am. Jur. 2d *Drugs and Controlled Substances* § 19 (2004); *see also United States v. Alveri*, 715 F. Supp. 1508, 1511 (M.D. Ala. 1989) ("To paraphrase Justice Douglas's rationale in *Freed*, one would hardly be surprised to learn that dispensation of drugs is an act involving substantial governmental concerns. . . . [T]his is Congress's legitimate prerogative.") (citing *United States v. Freed*, 401 U.S. 601, 609 (1971)).

This Court has repeatedly upheld federal regulation of the distribution of controlled substances as within Congress's Commerce Clause authority. *See Minor v. United States*, 396 U.S. 87, 98 n.13 (1969) (ban on sale of narcotics is within Congress's constitutional power); *Reina v. United*

States, 364 U.S. 507, 511 (1960) (Congress had "undoubted power to enact the narcotics laws"); *see also United States v. Tisor*, 96 F.3d 370, 375 (9th Cir. 1996), ("Controlled Substances Act does not exceed Congressional authority under Commerce Clause."); *United States v. Kim*, 94 F.3d 1247, 1250 (9th Cir. 1996) ("[E]very circuit that has considered a Commerce Clause challenge to § 841(a)(1) after *Lopez* has upheld the provision's constitutionality.").

Moreover, it is also black-letter law that Congress does "not abridge the reservation of police powers to the states under the Tenth Amendment by passing statutes prohibiting the possession and distribution of drugs." 25 Am. Jur. 2d *Drugs and Controlled Substances* § 19 (2004). *See Reina*, 364 U.S. at 511 (rejecting argument that state narcotic laws are "a subject that has traditionally been within the police power of the state" because "[t]he relevant inquiry here" is simply whether the federal action is "necessary and proper to the more effective enforcement of the undoubted power to enact the narcotics laws").[11]

As Judge Wallace's dissent makes clear, the majority's "argument that '*direct* control of medical practice in the states is beyond the power of the federal government' misses the point." *Ashcroft*, 368 F.3d at 1143 (quoting *Linder v. United States*, 268 U.S. 5 (1925)).[12] Both the Supreme Court

[11] *See also United States v. Lerebours*, 87 F.3d 582, 585 (1st Cir. 1996) (rejecting defendant's Tenth Amendment police powers argument because "courts will not strike down a statute under the Tenth Amendment where Congress was within its powers under the Commerce Clause to enact the statute"); *In re Grand Jury Proceedings*, 801 F.2d 1164, 1169 (9th Cir. 1986) (per curiam) (rejecting Tenth Amendment argument that the "control of medical practice is beyond the power of the federal government" because "the Commerce Clause empowers the federal government to regulate prescription drugs" and thus "physician may not defend a federal prosecution for improper drug prescription practices on Tenth Amendment grounds").

[12] The Ninth Circuit's reliance on *Lochner*-era cases to justify an unprecedented regulatory "opt out" right for individual states is entirely misplaced. The majority cited *Linder* as establishing a constitutional

and Ninth Circuit's "binding precedent compel the conclusion that Congress acts comfortably within its Commerce Clause power when it regulates the prescription and dispensation of controlled substances." *Id.* at 1143 (citing *Minor*, 396 U.S. 87, and *Reina*, 364 U.S. 507). Because "Congress' Commerce Clause power to prohibit physicians from prescribing controlled substances to assist suicide is not open to serious question[,] [t]hat ends the matter in this circuit and, of course, for this case." *Id.* at 1142 (citing *United States v. McCoy*, 323 F.3d 1114 (9th Cir. 2003)).

Indeed, respondents do not (and cannot) cite to a single currently-applicable case that would suggest there is a constitutional limitation on Congress's ability to exercise the full scope of its enumerated powers simply because it may have some effect on the practice of medicine. In fact, directly contrary to the respondents' assertions, this Court has applied the *Controlled Substances Act* in cases where its impact on the practice of medicine and state law was obvious without intimating the existence of any such constitutional limitation. *See United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 494-495 (2001) (*Controlled Substances Act* precludes recognition of a "medical necessity" defense for marijuana use despite California's determination that marijuana has medical utility); *Moore*, 423 U.S. at 139 (upholding *Controlled Substances Act* conviction of physician for illegally dispensing controlled substances from his medical practice).

Thus, because controlled substances are *not* "an area of law traditionally reserved for state authority" (see *supra* Part

prohibition against Congress's legislating in a way that affects "control of medical practice in the states." *Ashcroft*, 368 F.3d at 1124. However, *Linder*'s reliance on the *Lochner*-era doctrine that Congress could not employ its enumerated powers to accomplish general goals relating to health and welfare was expressly disavowed in *United States v. Darby*, 312 U.S. 100, 115-117 (1941) and has not been revived since.

I.A.1-I.A.5) and because the Attorney General's interpretation of 21 C.F.R. § 1306.04(a) does not "invoke[] the outer limits of Congress' power" or "push the limit of congressional authority" under the Commerce Clause, *Solid Waste Agency v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 172-173 (2001), the "clear statement rule does not apply" and this Court should evaluate the Attorney General's Directive "according to ordinary standards of deference." *Ashcroft*, 368 F.3d at 1143 (Wallace, J., dissenting).

United States v. Rutherford, 442 U.S. 544 (1979), also offers an instructive comparison. In holding that terminally ill cancer patients could not enjoin the United States from interfering with the interstate shipment and sale of Laetrile, Justice Marshall, writing for the Court, stated that "the construction of a statute by those charged with its administration is entitled to substantial deference." *Id.* at 553; *see id.* at 559 ("Whether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference.").[13]

The Court pointed out that "[s]uch deference is particularly appropriate where, as here, an agency's interpretation involves an issue of considerable public controversy, and Congress has not acted to correct any misperception of its statutory objectives." *Id.* at 554 (citations omitted). Justice Marshall concluded that "historical experience does suggest why Congress could reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise." *Id.* at 558.

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[13] *See also Oakland Cannabis Buyers' Coop.*, 532 U.S. at 491 n.4 (noting that "[e]limination of medical-necessity defense under Controlled Substances Act . . . does not require an explicit statement in the Act, as the Supreme Court will decline to set the bar so high, considering that . . . such a defense would entail a social balancing that is better left to Congress"); *cf.* Peter Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 50 Food & Drug L.J. 101, 103 (1995) ("Administration of the Act is and always has been largely a matter of judgment and discretion.").

Similarly, under the *Controlled Substance Act*, Congress has established comprehensive and uniform standards for the distribution of controlled substances and other dangerous drugs. These comprehensive and uniform standards are essential for the effective regulation of drugs in all fifty states. *See United States v. Rybar*, 103 F.3d 273, 284 (3d Cir. 1996) ("[F]ederal regulation of controlled substances [is] 'essential to effective control of the interstate incidents' of traffic in particular commodities.") (quoting *United States v. Kirk*, 70 F.3d 791, 796-797 (5th Cir. 1995)); c*f. Norfolk S. Ry. Co. v. Kirby*, 125 S. Ct. 385, 396 (2004) (O'Connor, J.) (citing *Romero v. International Terminal Operating Co.*, 358 U.S. 354, 373 (1959) ("[S]tate law must yield to the needs of a uniform federal maritime law when this Court finds inroads on a harmonious system[,] [b]ut this limitation still leaves the States a wide scope.").[14]

It is clear, however, that neither Oregon, nor any other state, may decide unilaterally to "opt out" of comprehensive and uniform federal regulations. *Cf. Testa v. Katt*, 330 U.S. 386, 393 (1947) (concluding that a state cannot "refuse to enforce the right arising from the law of the United States because of conceptions of impolicy or want of wisdom on the part of Congress in having called into play its lawful powers") (quoting *Minneapolis & St. L.R. Co. v. Bombolis*, 241 U.S. 211, 222 (1916)); *id.* at 391 ("[T]he Constitution and the laws passed pursuant to it are the supreme laws of the land, binding alike upon states, courts, and the people, 'anything in the Constitution or Laws of any State to the contrary notwithstanding.'") (quoting U.S. Const. Art. VI, § 2). Allowing such an unprecedented circumvention of federal law for any state that disagrees with a federal policy

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[14] Indeed, in this case, as Judge Wallace has pointed out, "[s]tate legislators may supplement the [Attorney General's] sanctions, and they may authorize alternative methods for assisting suicide that do not involve the prescription of controlled substances." *Ashcroft*, 368 F.3d at 1148.

would not only be antithetical to the Congressional objective of protecting public health and safety in this case, but also create an impracticable system of administrative law by establishing a dangerous precedent for future opt-outs.

CONCLUSION

For the foregoing reasons, the decision of the Ninth Circuit should be reversed.

Respectfully submitted,

RICHARD F. COLLIER, JR.
Collier & Basil, P.C.
100 Thanet, P.O. Box 3720
Princeton, NJ 08543
(609) 924-2213

DWIGHT G. DUNCAN
Counsel of Record
333 Faunce Corner Road
North Dartmouth, MA 02747
(508) 998-9600

COLBE MAZZARELLA
265 Essex Street, Suite 202
Salem, MA 01970
(617) 569-5971

THOMAS M. HARVEY
One Constitution Center
Boston, MA 02129
(617) 886-0364

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